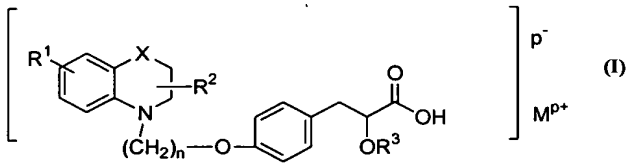
CLAIMS

1. Pharmaceutically acceptable salts of compound of the general formula (I)

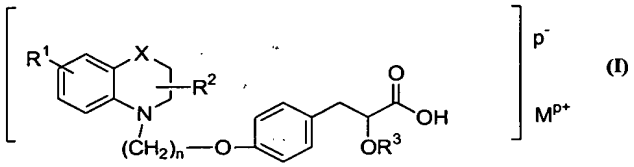


(I)

their derivatives, their analogs, their tautomeric forms, their stereoisomers, their polymorphs, wherein R^1 represents hydrogen, halogen, hydroxy, nitro, cyano or lower alkyl group; R^2 represents hydrogen, lower alkyl or oxo group; X represents a heteroatom selected from oxygen or sulfur; R^3 represents hydrogen or lower alkyl group; n is an integer ranging from 1-4; M represents a counter ion or a moiety which forms a pharmaceutically acceptable salt; p is an integer ranging from 1 to 2.

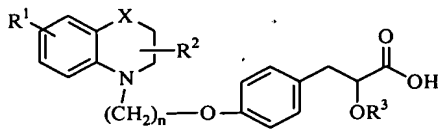
2. A compound as claimed in claim 1, where in the groups represented by M is selected from glucamine, N-methylglucamine, N-octylglucamine, dicyclohexylamine, methyl benzylamine, tris(hydroxymethyl)aminomethane, phenyl glycinol, lysine, aminoguanidine, aminoguanidine hydrogen carbonate or metformin.

3. A process for the preparation of pharmaceutically acceptable salts of compound of the general formula (I)



(I)

wherein R^1 represents hydrogen, halogen, hydroxy, nitro, cyano or lower alkyl group; R^2 represents hydrogen, lower alkyl or oxo group; X represents a heteroatom selected from oxygen or sulfur; R^3 represents hydrogen or lower alkyl group; the linking group represented by $-(CH_2)_n-O-$ may be attached either through a nitrogen atom or a carbon atom; n is an integer ranging from 1-4; M represents a counter ion or a moiety which forms a pharmaceutically acceptable salt; p is an integer ranging from 1 to 2, which comprises, reacting the compound of the formula (III)



(III)

where all symbols are as defined above with a stoichiometric amount of a base in the presence of a solvent.

4. The process as claimed in claim 3, wherein the base used is selected from glucamine, N-methylglucamine, N-octylglucamine, dicyclohexylamine, methyl benzylamine, tris(hydroxymethyl)aminomethane, phenyl glycinol, lysine, aminoguanidine, aminoguanidine hydrogen carbonate or metformin.

Amen. B1

5. The process as claimed in claims 3 and 4, wherein the solvent used is selected from an alcohol, ketone, ether, DMF, DMSO, xylene, toluene or a mixture thereof.

6. The process as claimed in claims 3 to 5, wherein the temperature of the reaction ranges from –10°C to the boiling point of the solvent employed for a period in the range of 10 minutes to 30 hours.

7. A compound according to claim 1, which is selected from :

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid lysine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid dicyclohexylamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid metformin salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid phenyl glycinol salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid methyl benzylamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid methyl benzylamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid methyl benzylamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid methyl benzylamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid methyl benzylamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid methyl benzylamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine hydrogen carbonate salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine hydrogen carbonate salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine hydrogen carbonate salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine hydrogen carbonate salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine hydrogen carbonate salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid amino guanidine hydrogen carbonate salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid tris(hydroxymethyl)aminomethane salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid tris(hydroxymethyl)aminomethane salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid tris(hydroxymethyl)aminomethane salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid tris(hydroxymethyl)aminomethane salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid tris(hydroxymethyl)aminomethane salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid tris(hydroxymethyl)aminomethane salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-octyl glucamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-octyl glucamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-octyl glucamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-octyl glucamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-octyl glucamine salt;

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-octyl glucamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-methylglucamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-methylglucamine salt;

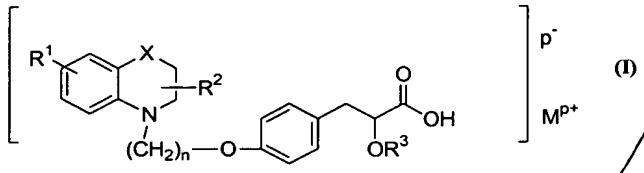
(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzoxazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-methylglucamine salt;

(±) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-methylglucamine salt;

(+) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-methylglucamine salt; and

(-) 3-[4-[2-(3,4-Dihydro-2H-1,4-benzothiazin-4-yl)ethoxy]phenyl]-2-ethoxy propanoic acid N-methylglucamine salt.

8. A composition, which comprises a compound of formula (I)



(I)

as defined in claim 1 or a compound as claimed in claim 7 and a pharmaceutically acceptable carrier, diluent, excipient or solvate.

9. A composition which comprises a compound of formula (I) as defined in claim 1 or a compound as claimed in claim 7 and an HMG CoA reductase inhibitor, fibrate, nicotinic acid, cholestyramine, cholestipol, probucol or a mixture thereof and a pharmaceutically acceptable carrier, diluent, excipient or solvate.

10. A composition as claimed in claims 8 and 9 in the form of a tablet, capsule, powder, syrup, solution or suspension.

11. A pharmaceutical composition as claimed in claims 8 and 9 for the treatment and / or prevention of type II diabetes, glucose intolerance, leptin resistance, dyslipidaemia, disorders related to Syndrome X such as hypertension, obesity, insulin resistance, atherosclerosis, hyperlipidemia, coronary artery disease and other cardiovascular disorders, certain renal diseases including glomerulonephritis, glomerulosclerosis, nephrotic syndrome, hypertensive nephrosclerosis, nephropathy, disorders related to endothelial cell activation, psoriasis, polycystic ovarian syndrome (PCOS), osteoporosis, inflammatory bowel diseases, myotonic dystrophy, pancreatitis, retinopathy, arteriosclerosis, xanthoma or cancer.

12. A method of preventing or treating hyperlipemia, hypercholesteremia, hyperglycemia, osteoporosis, obesity, impaired glucose tolerance, atherosclerosis, leptin resistance, insulin resistance or diseases in which insulin resistance is the underlying pathophysiological mechanism comprising administering a compound of formula (I) as defined in claim 1 or a compound as claimed in claim 7 or a pharmaceutical composition according to claim 8 or 9 to a patient in need thereof.

13. A method according to claim 12, wherein the disease is type II diabetes, impaired glucose tolerance, dyslipidemia, disorders related to Syndrome X including hypertension, obesity, insulin resistance, coronary artery disease and other cardiovascular disorders; renal diseases including glomerulonephritis, glomerulosclerosis, nephrotic syndrome, hypertensive nephrosclerosis, retinopathy, nephropathy, disorders to related endothelial cell activation, psoriasis, polycystic ovarian syndrome (PCOS), dementia, diabetic complications, inflammatory bowel diseases, myotonic dystrophy, pancreatitis, arteriosclerosis, xanthoma, eating disorders, cancer or osteoporosis or as inflammatory agents.

Amen. B3

14. A method according to claim 12, for the treatment and/or prophylaxis of disorders related to Syndrome X, which comprises administering an agonist of PPARα and/or PPARγ of formula (I) as claimed in claim 1 or a compound as claimed in claim 7 or a pharmaceutical composition according to claim 8 or 9 to a patient in need thereof.

15. A method of reducing total cholesterol, body weight, blood plasma glucose, triglycerides, LDL, VLDL or free fatty acids or increasing HDL in the plasma comprising administering a compound of formula (I), as defined in claim 1 or a compound as claimed in claim 7 or a pharmaceutical composition according to claim 8 or 9 to a patient in need thereof.

16. A method of preventing or treating hyperlipemia, hypercholesteremia, hyperglycemia, osteoporosis, obesity, impaired glucose tolerance, atherosclerosis, leptin resistance, insulin resistance, or diseases in which insulin resistance is the underlying pathophysiological mechanism comprising administering to a patient in need thereof an effective amount of a compound of formula (I) as defined in claim 1 or a compound as claimed in claim 7 or a pharmaceutical composition according to claim 8 or 9 in combination/concomittant with a HMG CoA reductase inhibitors, fibrates, nicotinic acid, cholestyramine, colestipol or probucol or their combination within such a period so as to act synergistically.

17. A method according to claim 16, wherein the disease is type II diabetes, impaired glucose tolerance, dyslipidemia, disorders related to Syndrome X such as hypertension, obesity, insulin resistance, coronary artery disease and other cardiovascular disorders; certain renal diseases including glomerulonephritis, glomerulosclerosis, nephrotic syndrome, hypertensive nephrosclerosis, retinopathy, nephropathy, disorders related to

endothelial cell activation, psoriasis, polycystic ovarian syndrome (PCOS), dementia, diabetic complications, osteoporosis, inflammatory bowel diseases, myotonic dystrophy, pancreatitis, arteriosclerosis, xanthoma, eating disorders, cancer or as inflammatory agents.

Amen. B4

18. A method according to claim 16, for the treatment and/or prophylaxis of disorders related to Syndrome X, which comprises administering to a patient in need thereof an agonist of PPARα and/or PPARγ of formula (I) as claimed in claim 1 or a compound as claimed in claim 7 or a pharmaceutical composition according to claim 8 or 9 and a HMG CoA reductase inhibitors, fibrates, nicotinic acid, cholestyramine, colestipol or probucol or their combination within such a period as to act synergistically.

19. A method of reducing plasma glucose, triglycerides, total cholesterol, LDL, VLDL or free fatty acids or increasing HDL in the plasma, which comprises administering a compound of formula (I) claimed in claim 1 or a compound as claimed in claim 7 or a pharmaceutical composition according to claim 8 or 9, in combination/concomittant with a HMG CoA reductase inhibitor, fibrates, nicotinic acid, cholestyramine, colestipol or probucol which may be administered together or within such a period as to act synergistically together to a patient in need thereof.

20. The process as claimed in claim 5, wherein the alcohol is selected from ethanol, methanol, isopropanol, butanol or a mixture thereof.

21. The process as claimed in claim 5, wherein the ketone is selected from acetone, diethyl ketone, methyl ethyl ketone or mixture thereof.

22. The process as claimed in claim 5, wherein the ether is selected from diethyl ether, ether, tetrahydrofuran, dioxane, dibutyl ether or a mixture thereof.

Add B5

add C1